HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-23

December 20, 2000

Albert M. Adams, President
Top Katch Seafood, Inc.
2380 N.E. 183rd Terrace
North Miami Beach, Florida 33160

Dear Mr. Adams:

On August 7-8, 2000, the Food and Drug Administration conducted an inspection of your facility located at 2380 N.E. 183rd Terrace, North Miami Beach, FL 33160. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA investigator observed serious deviations from the Seafood HACCP regulations. The FDA investigator discussed with you the import Seafood HACCP Report (Form 3502), and issued the List of Observations (FDA-483) which present his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follow:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for fresh snapper and all other fish and fishery products imported from Suriname;

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). Your firm selected the affirmative step for maintaining the foreign processor's HACCP plan and a written guarantee for snapper manufactured by [redacted] in [redacted] However, the written guarantee from [redacted] dated August 8, 2000 is not adequate because it does not guarantee that their seafood products were processed in accordance with the Seafood HACCP regulation.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to properly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Magda M. Karlsen, Compliance Officer, 6601 Northwest 25th Street (P.O. Box 59-2256), Miami, Florida 33159-2256. If you have questions regarding the implementation of the HACCP Regulations, you may contact Mrs. Karlsen at 305-526-2800 for the answers and/or directions towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

Jim E. Wathall

Emma R. Singleton
For Director, Florida District